

## Drugs recently approved or pending approval

### ALVESCO

The US Food and Drug Administration (FDA) has given approval to Nycomed (Florham Park, NJ) to market Alvesco (ciclesonide) inhalation aerosol for the maintenance treatment of asthma and as prophylactic therapy in patients aged 12 years and older. Alvesco was evaluated in 6 randomized, double-blind, placebo-controlled trials (N = 2843): 2 twelve-week once-daily dosing trials of patients maintained on inhaled bronchodilators and/or corticosteroids (studies 1 and 2), 1 trial of patients previously on bronchodilator therapy alone (study 3), 2 twelve-week trials of patients previously on inhaled corticosteroids (studies 4 and 5), and 1 twelve-week trial of patients previously on oral corticosteroids (study 6). Results of studies 1 and 2 suggested that once-daily Alvesco dosing was not optimal. Patients in study 3 received an AM dose once-daily of Alvesco 160 µg for 16 weeks; or twice-daily Alvesco 80 µg for 16 weeks or 4 weeks followed by an AM dose of once-daily Alvesco 160 µg for 12 weeks or placebo for 16 weeks. Patients in studies 4 and 5 received an AM dose of once-daily Alvesco 160 µg; twice-daily Alvesco 80, 160, or 320 µg; or placebo. Patients in study 6 received twice-daily Alvesco 320 or 640 µg or placebo. The primary endpoints were the mean change from baseline in pre-dose forced expiratory volume in 1 second (FEV<sub>1</sub>; studies 3–5) and reduction of oral corticosteroid use (study 6). All Alvesco doses showed statistically significant increases in AM pre-dose FEV<sub>1</sub> versus placebo (study 3, 5% and 10.4% with once- and twice-daily Alvesco 160 and 80 µg for 16 wk; 5% with twice-daily Alvesco 80 µg for 4 wk followed by 12-wk once-daily Alvesco 160 µg; study 4, 5.7% and 7.5% with once- and twice-daily Alvesco 160 and 80 µg; and study 5, 8.6% and 11.8% with twice-daily Alvesco 160 and 320 µg). In study 6, prednisone requirements decreased by 47% and 62% in patients treated with twice-daily Alvesco 320 and 640 µg, respectively, and increased by 4% in placebo-treated patients. The most common adverse effects were headache, nasopharyngitis, and sinusitis.



### INTELENCE

Tibotec Therapeutics (Raritan, NJ) has received FDA approval to market Intelence (etravirine) tablets to be used in combination with other antiretroviral drugs for treating HIV-1 infection in antiretroviral treatment-experienced adults who have evidence of viral replication and resistance to a nonnucleoside reverse transcriptase inhibitor (NNRTI) and other antiretroviral agents. Intelence was evaluated in 2 ongoing, 24-week, randomized, double-blind, placebo-controlled, phase 3 trials involving

1203 HIV-1-infected patients. Patients (plasma HIV-1 RNA > 5000 copies/mL while on a stable antiretroviral regimen for ≥ 8 wk; ≥ 1 NNRTI resistance-associated mutations; and ≥ 3 primary protease inhibitor mutations) received Intelence plus a background regimen (BR) or placebo plus a BR. All patients received darunavir/ritonavir and at least 2 other investigator-selected antiretroviral drugs (NNRTIs with or without enfuvirtide) as part of their BR. At week 24, 74% of Intelence-treated patients had HIV-1 RNA less than 400 copies/mL as compared with 51.5% of placebo-treated patients. The mean increase from baseline in CD4+ cell count was higher with Intelence versus placebo (81 versus 64 cells/mm<sup>3</sup>). The most common adverse effects were nausea and rash.

### TYSABRI

The FDA has given approval to Elan Pharmaceuticals, Inc. (San Francisco, CA) to market Tysabri (natalizumab) injection for inducing and maintaining clinical response (CR) and remission in adult patients with moderately to severely active Crohn's disease (CD). Tysabri was evaluated in 3 randomized, double-blind, placebo-controlled clinical trials (CD1, CD2, and CD3) involving

1414 patients with active CD (Crohn's Disease Activity Index [CDAI] score, 220–450). In CD1, patients were randomized 4:1 to 3 monthly infusions of Tysabri 300 mg or placebo. At week 10, 56% of Tysabri-treated patients achieved CR versus 49% of placebo-treated patients. In a post hoc analysis of a subset of patients with elevated C-reactive protein (CRP), 57% of Tysabri-treated patients achieved CR versus 45% of placebo-treated patients. In CD2, patients with elevated CRP were randomized 1:1 to 3 monthly infusions of Tysabri 300 mg or placebo. At weeks 8 and 12, 48% of Tysabri-treated patients achieved CR versus 32% of placebo-treated patients. In both CD1 and CD2, CR was defined as a greater than 70-point decrease in CDAI from baseline. In CD3, patients from study CD1 who responded to Tysabri at 10 and 12 weeks were re-randomized 1:1 to continuing monthly infusions of Tysabri 300 mg or placebo. After 9 months, 52% of Tysabri-treated patients maintained CR (CDAI < 220 and ≥ 70-point reduction in CDAI from baseline) versus 29% of placebo-treated patients. The most common adverse effects were headache, fatigue, and arthralgia.

*Compiled from press reports and pharmaceutical company press releases. For more information, contact Farrauh Charles, Hospital Physician, 125 Stratford Avenue, Suite 220, Wayne, PA 19087-3391.*

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